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10/500,493

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Samuel J Shuster

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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,493

Applicant(s)

SHUSTER ET AL.

Examiner

/Sean R. McGarry/

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-5 and 7 and the region defined by nucleotides 43-86 of SEQ ID NO: 1 in the reply filed on 5/22/07 is acknowledged. The traversal is on the ground(s) that each antisense compound does have common structure and function and would be interchangeable. This is not found persuasive because applicant has not provided any arguments or evidence to support these assertions where the restriction of record provides reasoning of why the antisense are indeed different in structure, for example. Furthermore applicant has neglected to address the prior art of record in the restriction requirement that destroys any special technical feature of the invention. Applicant is also directed to the art below that further shows this lack of a special technical feature linking the inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 and 8-15 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/22/07.

Claims 1-5 and 7 are examined in this Official Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 refers back to the composition of claim 2. Claim 3 adds the limitation of where the composition comprises a "plurality of isolated oligonucleotides, wherein each antisense oligonucleotide specifically hybridizes within a different accessible region" the language of the claim does not require that the oligonucleotides are targeted to TRPC, for example and renders the scope of the claim unclear. Furthermore it is unclear what is claimed when applicant uses the term "isolated antisense oligonucleotides" and then uses the term "each antisense oligonucleotide". The inconsistent use of terminology lends to alternative interpretations of the claims and renders it unclear. Furthermore the regions other than "43-86" have been withdrawn from the context of claim 1 which recites the regions in the alternative, for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1635

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al [WO 9965924].

Roberts et al disclose an oligonucleotide SEQ ID NO: 2054 that can be in combination with other oligonucleotides [a composition]. SEQ ID NO: 2-54 is 10 nucleobases in length and is complementary to the region defined by nucleotides 43-86 of SEQ ID NO: 1 of the instant invention. It is not disclosed that the oligonucleotide would inhibit TRPC4, but the oligonucleotide meets all of the structural requirements of the claim. The examiner is not equipped by the office to make such a determination and the burden is now properly shifted to applicant to show that the oligonucleotide would not function as required by the instant claims.

A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

“[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on prima facie obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Philipp et al [Applicant IDS citation “AK”].

Philipp et al disclose an expression vector, pCAGGS2-TRP4_{anti}, that expresses, under the control of a β actin promoter, an antisense trp4 [equivalent to TRPC4] transcript that inhibits the native form of TRP4. It is disclosed that the vector was transfected into SBAC cells (See "EXPERIMENTAL PROCEDURES" section on page 23966, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philipp et al [above] and Bennett et al [Biochimica et Biophysica Acta Vol. 1489:19-30, 1999].

The invention is as clearly set forth in the claim rejected.

Philipp et al have taught the inhibition of TRP-4 encoding nucleic acid via the expression of antisense transcripts in the study of TRP-4 function. Philipp et al have asserts that using an antisense strategy others have elucidated the function of TRP-1 and assert that more studies need to be performed to determine if TRP-1 interacts with TRP-4, for example (see last page, for example). Philipp et al have taught that it was known in the art to use antisense strategies to study TRP function and specifically teach the use of an antisense transcript in the study of TRP-4. It has been taught by the prior art that it is desirable and to inhibit TRP-4 via antisense in the study of its function, but Philipp et al do not specifically teach using antisense oligonucleotides to inhibit TRP-4.

Bennett et al provide a review paper, which indicates that antisense oligonucleotides are a valuable and general tool for use in gene function studies. Bennett taken with Philipp et al clearly provides one in the art the motivation to alternatively use an antisense oligonucleotide in place of an expressed antisense transcript where Philip et al have also recognized that the art has used antisense oligonucleotides in the study of TRP genes and protein function.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time of invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Sean R. McGarry/ whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean R McGarry/
Primary Examiner
Art Unit 1635